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Duncan E, Best C, Hagen S

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TABLE OF CONTENTS

[Intervention Review]

Shared decision making interventions for people with mental health conditions

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ABSTRACT

Background

One person in every four will suffer from a diagnosable mental health condition during their life course. Such conditions can have a devastating impact on the lives of the individual, their family and society. Increasingly partnership models of mental health care have been advocated and enshrined in international healthcare policy. Shared decision making is one such partnership approach. Shared decision making is a form of patient-provider communication where both parties are acknowledged to bring expertise to the process and work in partnership to make a decision. This is advocated on the basis that patients have a right to self-determination and also in the expectation that it will increase treatment adherence.

Objectives

To assess the effects of provider-, consumer- or carer-directed shared decision making interventions for people of all ages with mental health conditions, on a range of outcomes including: patient satisfaction, clinical outcomes, and health service outcomes.

Search methods

We searched: the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library* 2008, Issue 4), MEDLINE (1950 to November 2008), EMBASE (1980 to November 2008), PsycINFO (1967 to November 2008), CINAHL (1982 to November 2008), British Nursing Index and Archive (1985 to November 2008) and SIGLE (1890 to September 2005 (database end date)). We also searched online trial registers and the bibliographies of relevant papers, and contacted authors of included studies.

Selection criteria

Randomised controlled trials (RCTs), quasi-randomised controlled trials (q-RCTs), controlled before-and-after studies (CBAs); and interrupted time series (ITS) studies of interventions to increase shared decision making in people with mental health conditions (by DSM or ICD-10 criteria).

Data collection and analysis

Data on recruitment methods, eligibility criteria, sample characteristics, interventions, outcome measures, participant flow and outcome data from each study were extracted by one author and checked by another. Data are presented in a narrative synthesis.

Main results

We included two separate German studies involving a total of 518 participants. One study was undertaken in the inpatient treatment of schizophrenia and the other in the treatment of people newly diagnosed with depression in primary care. Regarding the primary

outcomes, one study reported statistically significant increases in patient satisfaction, the other study did not. There was no evidence of effect on clinical outcomes or hospital readmission rates in either study. Regarding secondary outcomes, there was an indication that interventions to increase shared decision making increased doctor facilitation of patient involvement in decision making, and did not increase consultation times. Nor did the interventions increase patient compliance with treatment plans. Neither study reported any harms of the intervention. Definite conclusions cannot be drawn, however, on the basis of these two studies.

Authors' conclusions

No firm conclusions can be drawn at present about the effects of shared decision making interventions for people with mental health conditions. There is no evidence of harm, but there is an urgent need for further research in this area.

PLAIN LANGUAGE SUMMARY

Shared decision making interventions for people with mental health conditions

Mental health conditions are common and can have serious consequences for both affected individuals and society. Current clinical guidance encourages mental healthcare practitioners to involve patients in treatment decisions. This is advocated on the basis that people have a right to self-determination and also in the expectation that it will increase treatment adherence.

We conducted thorough searches for randomised controlled trials (RCTs), quasi-randomised controlled trials (q-RCTs), controlled before-and-after studies (CBAs); and interrupted time series (ITS) studies of interventions to increase shared decision making in people with mental health conditions. We found two studies that met the inclusion criteria. Both studies were of good quality and made attempts to reduce potential sources of bias.

We examined whether interventions to increase shared decision making affected patient satisfaction with treatment or care, led to better health outcomes or to patients being less likely to be readmitted to hospital. One of the studies indicated that the intervention increased patient satisfaction in the short term. One study indicated that doctor facilitation of consumer involvement in decision making was increased by the intervention, but no effects were found on the clinical or health service outcomes in either study. Neither study reported that shared decision making for people with mental health conditions is harmful. However, no firm conclusions can be drawn from these two studies on any of the outcomes measured and further research is needed.

BACKGROUND

Mental illness

A quarter of the world's population will suffer from a diagnosable mental health condition during their life course (WHO 2001). For the purposes of this review, a mental health condition is deemed to be any diagnosis defined by recognisable criteria such as those included in the Diagnostic and Statistical Manual Version IV-TR (APA 2000) or the International Classification of Diseases (WHO 1992). Mental health conditions have a devastating impact on the lives of the people who experience them, their families and communities (WHO 2001). They can be personally debilitating and adversely affect a person's ability to work and participate in daily living, social and leisure activities. Moreover, caring for a family member who suffers from a mental health condition can lead to significant economic and emotional pressures. Unsurprisingly mental health conditions are classified as a national and international health priority topic (Scot Exec 2006; WHO 2001).

The recovery movement

The care and treatment of people with mental health conditions has evolved considerably over the last 400 years; from a model of social persecution and ostracism, to a model of social care, through a period of medicalisation, to the present day where consumers are increasingly recognised as central to care and health improvement is viewed in terms of recovery, rather than simply symptom relief. The recovery model of mental health recognises that patients have a drive to find meaning and purpose in life. Evolving from international service user movements, the recovery model emphasises control being placed in the hands of the individual and not the professional (Jacobson 2001); this has now been adopted at a national policy level in several countries (CMHS 2004; CMHS 2006; Scot Exec 2006). Taking a recovery model perspective of care requires greater emphasis on the collaborative nature of care between providers, consumers and their families. The individual's right to autonomy and self-determination is fundamental to this perspective.

Decision making

Paternalism has, until relatively recently, been the dominant model of decision making within health care. There have been exceptions to this and alternative models of power sharing in medical relationships were promulgated as long as 50 years ago (Balint 1957; Engel 1960). However, despite calls for change throughout the 1970s (Veatch 1972) and 1980s (Brody 1980; Quill 1983), alternative approaches to decision making in health care did not truly gather pace until the 1990s (Adams 2006; Charles 1997; Frosch 1999).

One alternative to the paternalistic model of decision making is the 'informed decision making' model. In this model, professionals are viewed as technical experts whose role it is to impart information to patients, who then have responsibility for making any treatment decisions. Another decision making model is the 'professional as agent' model. Here, the professional either assumes to know, or elicits, the preferences for treatment of the patient and makes a decision based on both technical knowledge and knowledge of patient preferences. Neither of these models can be considered models of shared decision making. This is because informed decision making excludes the preferences of the professional so is not a shared decision. The 'professional as agent' model relies on the professional determining patient preferences and including these in the decision. This too is not shared decision making as it is known that the professional may not accurately gauge patient preferences (Gafni 1998). The patient's perspective may therefore not truly be involved in the decision. Shared decision making (SDM) instead requires the sharing of treatment preferences and decisions by both the professional and the patient (Charles 1997).

Shared decision making

The concept of SDM has suffered from being variably and loosely defined in the literature (Clayman 2009). Despite the conceptual work of Charles 1999, Coulter 1997, Elwyn 1999, Towle 1999, Trevena 2003 and others, when Makoul and colleagues reviewed the definitions of SDM used in 418 articles on the subject, they found that inconsistency of definition and in many cases no reference to preceding work (Makoul 2005). Makoul 2005 proposed an integrative model of SDM that built upon the most widely used definitions. For a decision to be a 'shared' decision it has to have certain characteristics. It must involve at least two participants, and the sharing of information. The decision (which may be to do nothing) must be made and agreed upon by all parties (Charles 1997). Trevena 2003 identified that the suitability of a decision for SDM depends upon the clinical context, patient preferences, and practitioner responsibilities. Montori (Montori 2006) examined Charles' (Charles 1997) SDM model in relation to long-term conditions and concluded that for SDM to work in these conditions it was necessary to add another component to the model: "ongoing partnership between the clinical team (not just the clinician) and the patient" (p.25).

Whilst SDM research is now well established, its focus to date has been on physicians dealing with physical conditions, often in primary care (e.g. Davis 2003; Elwyn 1999). SDM for people with mental health conditions has been less well evaluated. Adams 2006 argued that whilst there is examination of professional-patient partnerships, patient education and other interventions that may contain elements of SDM, there are few studies that have:

- assessed patients' desire and ability to participate in SDM;
- evaluated training of professionals to adopt SDM;
- developed SDM interventions; or
- measured the effects of SDM in mental health settings.

In short, the impact of SDM for people with mental health conditions is largely unstudied in isolation from other factors. There has, however, been some work in this area. Hamann 2003 conducted a review of SDM in psychiatry and identified four relevant studies. Three related to the choice of treatment options (Bedi 2000; King 2000; Rokke 1999) and the fourth examined the decision to continue or discontinue psychotropic medication (Bunn 1997). Hamann 2003 reports that only Bunn 1997 employed an adequate model of SDM. Both the paucity of studies and methodological issues with the studies themselves means that no firm conclusions can be drawn from Hamann's review about the effects of SDM interventions. Significant time has passed since the review's publication and, this being an emerging field, it was felt that new evidence available about SDM interventions for mental health conditions may be available. Furthermore the search strategy of the current review was more inclusive than that conducted by Hamann 2003.

Marshall and colleagues (Marshall 2005) published a review of patient involvement and collaboration in SDM that focused on

chronic disease management. Their review included 146 articles representing 137 studies. However the overall poor quality of reporting of these studies made data extraction and quality assessment difficult. The authors found that across all conditions, interventions to increase collaborative care had a positive effect on patient satisfaction and health outcomes, particularly in the short term. They also found great diversity in the interventions and outcome measures used in the identified studies. Only 11% of included articles focused on mental health conditions and no subgroup analysis was conducted on them. The authors acknowledge that the majority of articles included in the review were of medical decision making, and highlight that studies of multidisciplinary care or care by nurses or allied health professionals were lacking. Marshall 2005 was limited in the range of sources searched. A broader, more inclusive approach may retrieve relevant literature from other sources.

There are a number of related systematic reviews which have been published or are underway. Lewin 2001 (presently being updated) examined interventions to promote a patient-centred approach in clinical consultations, and Peri (Peri 2006) is currently reviewing the literature on goal setting in physical rehabilitation for older people. Patient-centred care is hard to define but includes shared control of consultations and a focus on the whole person (Lewin 2001). However, whilst patient-centred care is the context of SDM, and goal setting can be a part of SDM, neither is synonymous with SDM and in neither review is the target population people with mental health conditions. SDM focuses solely on the process of treatment decision making whereas patient-centred care covers the tailoring of care to the individual's needs and preferences in addition to patient involvement in care (Robinson 2008). A number of recent articles have highlighted the need for more research into SDM specifically in mental health settings (Deegan 2006; Schauer 2007; Wills 2006). To date there has not been a comprehensive review of SDM interventions for people with mental health conditions.

Shared decision making interventions

A variety of interventions include elements of SDM, although they do not comprise all the features of SDM noted by Charles 1997 (see Types of interventions). Examples of these are:

- including the patient in the decision making process (for example, listening, finding out what the patient already knows, involving patients in the definition of the problem, ensuring that patients understand the clinical problem and the nature of the decision required);
- exploring patients' worries, fears and expectations (for example, discussing uncertainties, providing opportunities for questions, and setting goals);
- discussing potential treatment options (for example, agreeing levels of involvement in the decision making process - which may result in patients deciding they do not wish to be involved, discussing intervention options considering risks and benefits);
- providing information (for example, communicating risk, providing information about interventions, discussing pros and cons);
- ensuring information is understood (for example, discovering the level of a patients' understanding about a condition and the intervention options, obtaining patients' views about intervention);
- ensuring patients are happy with the decision making process and the decisions made (for example, encouraging patients to be involved in actioning intervention plans, asking patients' preferences);
- and providing opportunities to review decisions made (Braddock 1997; Edwards 1999; Elwyn 2005).

The importance of having effective, individualised and comprehensive care which directly involves mental health service users in the decision making process has been well recognized (Sainsbury 1998). SDM is being incorporated into healthcare policy and practice both in the UK and internationally (DoH 2007; IoM 2006; Siriwardena 2006). Despite this, there is limited knowledge about the quality and effectiveness of SDM interventions for mental health conditions.

People can experience a range of mental health conditions throughout their life span, and be treated in various settings, ranging from primary care to secure services. Whilst the specific needs of clients with varying diagnoses may differ, the processes of care are broadly similar regardless of age, setting, or clinical condition. Frequently a client's care is not decided by the client and professional in isolation. Friends, family or carers may all have an interest in a client's care; some may act as advocates for the client or actively participate in the care process. This review focused on the effectiveness of SDM interventions with clients of all ages who have a mental health condition, regardless of treatment setting. Studies where decisions involving family members or carers are the target of the SDM intervention were included. Subgroup analysis of these differentiating factors was to be conducted were sufficient data extracted.

OBJECTIVES

To assess the effects of provider-, consumer- or carer-directed shared decision making (SDM) interventions for people of all ages with mental health conditions, on a range of outcomes including: patient satisfaction, clinical outcomes, and health service outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

We aimed to include:

- randomised controlled trials (RCTs),
- quasi-randomised controlled trials (q-RCTs),
- controlled before-and-after studies (CBAs); and
- interrupted time series (ITS).

We included study designs other than RCTs in our criteria because conducting RCTs is sometimes not feasible in this field, and valuable data may be excluded by stringent criteria regarding research design. However had there been sufficient well-designed RCTs which met all selection criteria, then other study designs would have been excluded.

Comparison groups, for included studies, were those composed of participants not receiving a specific SDM intervention. Trials comparing the effects of two different SDM interventions with

people who experience mental health conditions would also have been included.

Types of participants

The people receiving the healthcare service within studies were those diagnosed with a mental health condition by any defined criteria such as the International Classification of Diseases (WHO 1992) or the Diagnostic and Statistical Manual of Mental Disorders (APA 2000). We included studies enrolling individuals of all ages. We included public and private healthcare consumers.

We excluded studies that focused on people with substance misuse problems where comorbid mental health conditions had not been assessed using DSM or ICD-10 criteria.

The participants involved in the intervention were professionals, service users, family and/or carers.

Types of interventions

Included studies may have assessed a single intervention or a combination of interventions, and may have compared them with other interventions with a similar purpose, or with usual care. An intervention was included if its description was sufficient to allow review authors to determine that it aimed to increase the degree of SDM between patient and provider. For a decision to be classified as 'shared' it had to involve at least two participants, information must have been shared between participants, both parties must have participated in the decision making process, and a decision must have been made or been actively deferred (Charles 1997). Studies were included if they focused on enhancing any aspect of these four criteria identified by Charles (Charles 1997), providing that two parties were involved in making a decision, and the decision was not about future crisis care, i.e. advanced directives. Studies that met all four of Charles' criteria were differentiated from those that addressed less than four of the criteria, and this was recorded at data extraction.

The review included interventions targeted at providers (such as training in problem definition and agreement, presenting options), consumers (such as those which enhance participation, involvement or autonomy), or carers or family members. Interventions could take place in any environment and were not restricted by the mode or intensity of delivery.

We included studies that had interventions provided by a wide range of mental health service providers (including general practitioners, psychiatrists, psychologists, nurses, social workers, occupational therapists and other allied health professionals, and lay support staff working in mental health settings).

We excluded any intervention which:

- was primarily a secondary intervention (for example, anxiety management);
- consisted solely of information provided to patients about a condition (for example patient education without the two-way sharing of information necessary for SDM);
- was aimed at enhancing communication between patient and provider, without focus on a particular choice or decision; or
- was targeted at future care; that is, advanced directives, also known as Ulysses contracts that set out how a person who is periodically mentally unwell wishes to be treated at those times.

Types of outcome measures

Primary outcomes

The following measures were chosen to cover the consumer-based, health and service use categories:

- Patient global satisfaction (measurement tools of patient global satisfaction could include instruments such as the Client Satisfaction Questionnaire-8 (Attkisson 1982));
- Clinical outcomes (measurement tools for clinical outcome could include depression scales such as the Beck Depression Inventory (BDI II; Beck 1996) or the Patient Health Questionnaire -9 (PHQ 9; Kroenke 2001); met and unmet needs scales such as the Camberwell Assessment of Need (Slade 1999); levels of psychosocial functioning scales such as the Global Assessment of Functioning (GAF; Jones 1995) or the Health of the Nation Outcome Scales (HONOHS; Wing 1996); or anxiety scales such as the State-Trait Anxiety Inventory (STAXI; Spielberger 1983));
- Health service outcomes (e.g. rate of readmission to hospital).

Secondary outcomes

The secondary outcomes and their related measures were:

- Level of consumer involvement in the decision-making process (for example, observing patient involvement scale (OPTION; Elwyn 2003); Patient's Perceived Involvement in Care Scale (Lerman 1990));
- Consumer satisfaction with decision (for example, Satisfaction with Decision Scale (Holmes-Rovner 1996));
- Consumer satisfaction with information provided (measures of the consumer's satisfaction with information provided, for example that developed by the Swedish Institute (Swedish Inst 1993))`
- Consumer experience of patient-provider interaction (for example, Stewart 1999);
- Consumer quality of life (for example, World Health Organisation Quality of Life Scale (WHOQOL-100; Skevington 1999));
- Consumer knowledge;
- Provider knowledge;
- Provider satisfaction;
- Family/carer satisfaction;
- Family/carer experience of family/carer-provider interaction;
- Family/carer involvement in the decision-making process;
- Consumer concordance with treatment plan;
- Consultation time;
- Intent to change health behaviour;
- Other service outcomes (e.g. length of hospital stay).

Search methods for identification of studies

We:

1. Searched electronic bibliographic databases for published work;
2. Searched trial registers and asked contact authors for information on ongoing and recently-completed studies;
3. Searched the reference lists of relevant published studies; and

4. Contacted authors of relevant studies to check for additional studies.

There were no language restrictions.

Electronic searches

We used an explicit search strategy, developed in collaboration with the Cochrane Consumers and Communication Group, to search the following bibliographic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL), *The Cochrane Library* 2008, Issue 4;
- Cochrane Consumers and Communication Review Group Specialised Register (December 2008);
- Centre for Reviews and Dissemination Databases (Database of Abstracts and Reviews of Effects (DARE), Health Technology Assessment (HTA) Database, and the Ongoing Reviews Database) (September 2008) with the terms (shared decision making) and (mental health or psychiatry);
- MEDLINE (Ovid) (1950 to November 2008);
- EMBASE (Ovid) (1980 to November 2008);
- PsycINFO (Ovid) (1967 to November 2008);
- CINAHL (Ovid) (1982 to November 2008);
- British Nursing Index and Archive (1985 to November 2008)
- SIGLE (Open SIGLE at INIST (http://opensigle.inist.fr) (1890 to September 2005 (database end date) with the terms (shared decision making) AND (mental health).

The search strategy was structured according to a study design filter, mental illness search terms (based on advice from the Cochrane Depression, Anxiety and Neurosis Review Group, and the Schizophrenia Review Group), and shared decision making terms (Makoul 2005). We present the search strategy for MEDLINE in Appendix 1; EMBASE in Appendix 2, PsycINFO in Appendix 3, CINAHL in Appendix 4, and the British Nursing Index and Archive in Appendix 5.

Ongoing and recently completed clinical trials

The ReFeR database is no longer supported by the Department of Health ReFer so this was not searched although the protocol (Duncan 2008) had stipulated it would be. Instead we searched the National Research Register (WHO Clinical Trial Portal (http://www.who.int/trialsearch) in November 2008 with the terms (shared decision making) and (mental health or psychiatry).

We also searched the International Register of Controlled Trials (http://www.controlled-trials.com/isrctn/) in November 2008 (with the terms (shared decision making) and (mental health or psychiatry).

Additionally we contacted study authors of ongoing and recently-completed clinical trials to obtain details of unpublished studies.

Searching other resources

Searching reference lists

We searched the reference lists of relevant published studies and reviews for studies not already assessed for inclusion in this review.

Contacting study authors

Where required, we contacted authors of relevant studies for further information about their studies, and to ask whether they were aware of any other complete or ongoing studies meeting our inclusion criteria.

Data collection and analysis

Selection of studies

Two review authors conducted the searches and initial screening of studies (using titles and abstracts) for possible inclusion. Study author names were not masked during screening. We retrieved full text copies of all articles judged to be potentially relevant to the review, and two review authors independently assessed these for inclusion. Any differences in judgement were reconciled through discussion between two review authors and, where consensus was still not reached, with the third author. Where a study had insufficient information to allow a decision to be made, we contacted the authors of the study to obtain further information to enable the study to be definitively included or excluded. Any study excluded at this stage was listed in the table Characteristics of excluded studies and the reason for exclusion given.

Data extraction and management

Two review authors extracted data independently from all included studies using a standard form derived from the data extraction template of the Cochrane Consumers and Communication Review Group (DET 2007), reconciling differences by discussion and, where consensus could not be reached, with the third author. A copy of the adapted data extraction form is available from authors on request.

The data extraction form included a measure of whether SDM criteria (Charles 1997) were partially or completely met.

For each study, we extracted the following data on outcome measures:

• name of outcome measure;
• method of data collection used to assess each measure (e.g. questionnaire, interview, observation);
• outcome data at immediate (up to 1 month), 3, 6, 12, 18 and 24 month follow up; and
• adverse incidents (e.g. complaints about outcome measurement, other adverse incidents).

We extracted the results of each study in terms of outcome measures' means, standard deviations (SD), number of events, percentages (N), significant and non-significant differences, and P values.

If reliable data could not be extracted from a study then we contacted the study authors, and if the data were not available then the study was recorded as an included study without data. Data were checked and entered into RevMan by one review author and checked after entry by a second author.

Assessment of risk of bias in included studies

We assessed and reported on the methodological quality of included studies in accordance with the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2007), which recommends the explicit reporting of the following individual

quality elements for RCTs: randomisation; allocation concealment; blinding (participants, providers, outcomes assessors, data analysts); baseline comparability; methods used to re-establish contact with participants lost to follow-up; intention-to-treat analysis; validation of tools; and other sources of bias, for example skewed data. We assessed skewed data in accordance with the guidelines in the Cochrane Handbook (section 8.5.2.11, Deeks 2006; Higgins 2006). It was planned to assess q-RCT, CBA and ITS studies systematically for quality in accordance with the criteria outlined by the Cochrane Consumers and Communication Review Group. Had sufficient studies with comparable outcome measures, been found, we planned to conduct a sensitivity analysis based on study quality. Studies of low quality would have been removed from the analysis in order to assess the effect on the results.

In all cases, two review authors independently assessed the quality of included studies, with any disagreements resolved by discussion and consensus. We contacted study authors for additional information about the included studies, for example clarification of the study methods. We incorporated the results of the quality assessment into the review through systematic narrative description and commentary about each of the quality items, leading to an overall assessment of the quality of included studies and a judgement about the internal validity of the review's results.

Measures of treatment effect

Once the previous steps of the review had been completed, we analysed the included studies to determine whether there were any studies sufficiently similar in design, setting (e.g. in-patient, community mental health team, etc), age, intervention, and outcome measurement to allow their data to be combined for meta-analysis. This proved not to be possible due to the two included studies having different settings, inclusion criteria and interventions. Details of how the data would have been analysed had enough high quality studies been identified are detailed below, and will be applied in future updates of this review if appropriate.

For studies with continuous data, we planned to report mean differences with 95% confidence intervals where these data were available. Where studies used different assessments to measure the same concept (e.g. anxiety levels), we planned to report the standardised mean difference (SMD). We note that there are difficulties in interpreting findings regarding differences in SMDs since they cannot easily be related back to the original assessment scales.

For dichotomous data, in studies that had measured outcomes in a standard way, we planned to report the risk ratio and confidence intervals. It was intended to take a cautious approach to combining results throughout, and outline in the review the rationale for doing so. A meeting of all review authors decided whether there was sufficient homogeneity of interventions, participants or outcomes to enable meta-analysis to take place. As the subject matter of this review is broad in nature, we expected that meta-analysis would only be feasible for a few, if any, subgroups of participants, interventions or outcomes. Where studies were found to be heterogeneous in design, intervention or in outcome measures used, we planned to conduct a descriptive review of included studies, and present it using both a narrative summary and presentation of extracted data in tables and figures as appropriate.

Unit of analysis issues

It was determined in advance, that cluster randomised trials would not be analysed directly with non-cluster trials, in order to avoid a unit of analysis error.

Dealing with missing data

We planned to use an intention-to-treat (ITT) analysis, where data would be analysed based on the treatment condition a participant was allocated to rather than the treatment they received, or whether they were lost to follow up. We contacted study authors for missing statistical data.

Assessment of heterogeneity

We planned to assess statistical heterogeneity visually with a forest plot. The presence or absence of overlapping confidence intervals would indicate whether the variation observed in the results was likely to be explained by chance alone. Heterogeneity was also planned to be assessed using the Chi^2 test. A significance level of P = 0.1 would be used in view of the low power of such tests.

It was intended that in the absence of overlapping confidence intervals and where chi-square tests indicated heterogeneity, the level of heterogeneity would be examined further by calculating I^2 (Higgins 2002). I^2 values of 50% and more indicate a substantial level of heterogeneity (Higgins 2003; Higgins 2006).

Assessment of reporting biases

It was intended that we would assess publication bias graphically through a funnel plot. We acknowledge the limitations of such analysis and if asymmetry was found we planned to examine other possible interpretations such as clinical heterogeneity before concluding publication bias was present (Section 8.11.1 Publication bias and funnel plots Cochrane Handbook for Systematic Reviews of Interventions (Deeks 2006)).

Multiple publications were collated and assessed as one study.

Data synthesis

We planned that, where there were enough suitable studies, meta-analysis would be conducted using a random-effects model.

Subgroup analysis and investigation of heterogeneity

Potential subgroup analysis would include:

- study design;
- the environmental setting of the intervention (e.g. inpatient, outpatient, primary care, community, secure environment);
- diagnosis (e.g. depression, schizophrenia, anxiety etc);
- age groups (e.g. children (0 to16), adult (16 to 65) and elderly (over 65));
- intervention type (e.g. to providers, consumers or carers); and
- outcome measurement (patient satisfaction or clinical outcome).

If substantial heterogeneity was found, we planned to determine potential reasons for the heterogeneity by examining individual study characteristics and those of subgroups of the main body of evidence.

Sensitivity analysis

We planned to perform sensitivity analyses in order to explore the influence of the following factors on effect size:

1. study quality (excluding studies identified as being of poor quality); and
2. excluding outliers.

We also planned to test the robustness of the results by repeating the analysis using different statistical models (fixed-effect and random-effects models). The proposed number of analyses was restricted as we anticipated a small number of studies would be included in any meta-analysis and repeated testing would be inappropriate in that context.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

In May 2008 we searched MEDLINE, EMBASE, PsycINFO, CINAHL and the British Nursing Index and Archive; generating 2886 references after duplicates were removed. After evaluation of these references by title and abstract, we retrieved 188 papers in full text. In September 2008 we searched SIGLE (726 hits), CENTRAL and the CRD databases (4 hits), none of the results were eligible for full text assessment. In November 2008 we updated the searches of MEDLINE, EMBASE, PsycINFO, CINAHL and the British Nursing Index and Archive (see Appendices for search output) and identified a further 5 studies for full text assessment. In December 2008 we searched the National Research Register and the International Register of Controlled trials and identified no studies meeting the inclusion criteria, nor were any identified from a December 2008 search of the Cochrane Consumers and Communication Review Group's specialised register. We identified no additional papers from the reference lists of published articles or from contacting the investigators of the included studies.

We identified and retrieved a total of 197 articles for appraisal in full text.

Included studies

Three papers describing two studies met the inclusion criteria (Hamann 2006 (two papers); Loh 2007a). Both studies were conducted in Germany which reflects German Ministry of Health funding to the research consortium 'Patient as partner in medical decision making'.

Contact with authors

Drs Hamann (Hamann 2006), Loh (Loh 2007a), and Malm (Malm 2003) were very helpful in providing additional information about their studies.

Sample sizes

Hamann 2006 recruited 113 patients and Loh 2007a 405 patients.

Setting

The two studies were conducted in different settings in Germany. Hamann 2006 was conducted in an acute inpatient setting: 12 acute psychiatric wards of two state hospitals. Participants were followed up for eighteen months post-discharge. Loh 2007a was conducted out of hospital, in the community, and recruited primary care patients. One hundred and eighty eight primary care physicians were approached and thirty were recruited to the study.

Participants

Participants in Hamann 2006 were inpatients with a diagnosis of schizophrenia or schizoaffective disorder. On average they had been unwell for around nine years and had five previous admissions. They participated in the study while on an acute ward once their condition had stabilised sufficiently to meet inclusion criteria (a score of < 5 on the conceptual disorganisation scale of the Positive and Negative Syndrome Scale for schizophrenia (PANSS)). The investigators state that "acute psychotic derangement was not considered an exclusion criterion; rather, physicians were instructed to include all patients at the earliest stage possible" (personal communication).

The participants in Loh 2007a were primary care patients newly diagnosed with depression.

Interventions

There was much common ground between the study interventions. Both study interventions included a decision aid. In the Hamann 2006 study the patients used a decision aid with support from nursing staff and then took the information with them to a planning meeting with their psychiatrist. The decision aid contained information about pharmacological and psychoeducational treatment options. Patients recorded their previous experiences with medication and treatment preferences in the decision aid. Completing the documentation took between 30 and 60 minutes. In the Loh 2007a study the patients used a decision board during the consultation with their physician and then took it away with them. The Loh 2007a decision aid included information about the disorder, treatment options, advantages and disadvantages of treatment options, and support for patient value clarification. It also contained positive encouragement for patients to be active in the decision making process.

In Hamann 2006 the ward nurses received training on how to help the patients work through the decision aid documentation.

In both studies the physicians received training. In Hamann 2006 the physicians received two information sessions on SDM and the communication skills they should apply as part of the intervention. In Loh 2007a the physicians completed modules on guideline concordant depression care. They also received training on how to involve patients in the decision making process. For the physicians participating in the Loh 2007a study there were five scheduled training events over a six month period.

Comparison group

In the Hamann 2006 study the intervention involved working through the decision aid with a nurse, and taking this to a planning meeting with the psychiatrist. Both of these elements were absent in the usual care condition. Control participants did not receive a decision aid and had no time set aside for them to discuss

their ongoing treatment with their psychiatrist, although it should be noted that there was no significant difference between the amount of time the control and intervention psychiatrists spent with patients. In the Loh 2007a study the usual care participants received no decision board and their physician did not received training in SDM.

Definitions of SDM

The authors of Hamann 2006 cite Charles 1997 for their definition of SDM. The authors of Loh 2007a state that their approach to training physicians was based on the work of Towle 1999 and Elwyn 1999.

Study design

Both included studies were cluster randomised controlled trials. In Hamann 2006 the unit of randomisation was the ward and in Loh 2007a it was the physician.

In both studies the intervention and control groups were not matched at baseline, and both studies controlled for differences in baseline characteristics statistically. The Hamann 2006 study used a cohort design in which the same patients were tested pre- and post-intervention. The patients were recruited to the study after they were admitted to an acute psychiatric ward. A large proportion of eligible participants were discharged before they could be recruited to the study. All participants had baseline measures taken. Patients in the control group were reported to be treated as usual. Patients in the intervention group were introduced to the decision aid, followed by a planning talk with their psychiatrist. Outcome data were collected after the interview with the psychiatrist, at discharge and then 6 and 18 months post-discharge.

In the Loh 2007a study, two different sets of patients were recruited pre- and post-intervention. Pre-intervention, patients of physicians were recruited, the patients consulted with their physician and measures of satisfaction, clinical improvement (over 6 to 8 weeks) and compliance were made. The intervention physicians then received their training in SDM. Then, the intervention and control physicians recruited another set of patients who were assessed on the same set of outcomes post-consultation. The investigators found high intra-cluster correlations (i.e. much of the variation in outcome was due to the physician) which was statistically controlled for using Analysis of Covariance (ANCOVA).

Excluded studies

Twenty three excluded studies are reported in the Characteristics of excluded studies table. One of the most common reasons for exclusion was that the SDM intervention was part of a complex intervention addressing many facets of patient care. In these studies the effects of SDM intervention could not be isolated.

Risk of bias in included studies

Randomisation

In Hamann 2006, randomisation was at the level of the ward. Twelve acute psychiatric wards of two state hospitals were divided into six pairs of wards, one of which was randomly assigned to the control and one to the intervention condition. The investigators state that the pairs of wards had the same management and catchment area, and were 'comparable' in terms of distribution of diagnoses, number of beds, number of physicians and nursing staff and the usual route of admission. Wards were paired before being allocated to intervention or control condition so this is not truly random.

In Loh 2007a, the thirty physicians drew blinded lots to determine whether they were in the intervention or control condition. This is an adequate method of randomisation.

Allocation concealment

Both studies were cluster randomised controlled trials. The method of randomisation was the ward in Hamann 2006, and the physician in Loh 2007a. These designs may make it unfeasible to have true allocation concealment at the level of the patient. In Hamann 2006 it would have been possible to influence which ward a patient was admitted to, particularly if there was more than one ward with a vacancy. In the Loh 2007a study it would be possible for physicians to influence which of their patients are identified for recruitment to the study.

Blinding

Due to the nature of the interventions, blinding of the health professionals delivering the intervention was not possible in either study. In the Hamann 2006 study, the participants, providers and outcome assessors were not blinded. It is unclear whether data analysts were blinded. In the Loh 2007a study, the providers, outcome assessors and data analysts were not blind, but the participants were.

Validation of tools

The studies used a mixture of validated and unvalidated instruments.

Baseline comparability

Neither study had adequate baseline comparability between intervention and control participants. Both studies controlled for this statistically.

Loss to follow up

In the first part of the Hamann 2006 paper, the participant flow chart gives the number of patients who withdrew consent after joining the study (five (9%) in the intervention group and one (2%) in the control group). However the Hamann 2006 results table (Table 1) indicates the total numbers lost to follow up (not just withdrawals). The number of respondents for control and intervention groups combined is: for Combined Outcome Measure for Risk Communication and Treatment Decision Effectiveness (COMRADE) after intervention n = 75 (66%), COMRADE before discharge n = 82 (73%), knowledge before discharge n = 88 (78%), and patient global satisfaction ZUF-8 n = 83 (73%). In the longer-term follow up (2007 data, see Hamann 2006) data were unavailable for 71 participants (66%).

In Loh 2007a the intervention arm enrolled 263 patients of which 72 (27%) were lost to follow up and the control arm enrolled 142 patients of which 46 (32%) were lost to follow up.

Further information on risk of bias in the included studies is reported in Characteristics of included studies.

Effects of interventions

Primary outcomes

Patient global satisfaction

The Hamann 2006 study did not find any difference between groups in terms of satisfaction. Loh 2007a found a statistically significant increase in levels of satisfaction in the intervention group (P = 0.014).

Clinical outcomes

Neither study found effects on clinical outcomes. In Hamann 2006 there was no statistically significant difference in PANSS scores between the intervention and control groups when they were discharged from hospital. Nor was there any difference in their Clinical Global Impressions scale or GAF scores at 6 and 18 months post-discharge. In Loh 2007a the two groups showed similar improvement in PHQ depression score in the 6 to 8 weeks after visiting their physician.

A factor that may have mitigated against finding an effect of the intervention was the conservative nature of the study design used by Loh 2007a. Recruiting different patient samples for pre and post intervention introduced a high level of variance in outcome between patient groups over and above any treatment effects.

Their data were analysed using ANCOVA controlling for intra cluster correlation, patient age, family status and education level. This would have controlled for pre-existing differences between physicians but not for difference between the groups of patients recruited pre and post intervention. To illustrate this, the control physicians achieved a 12.4% (47.8 SD) reduction in severity of depressive symptoms over 6 to 8 weeks in their first group of patients and a 45.9% (34.2 SD) reduction in their second. As these physicians received no intervention this is due to the different characteristics of the two groups of patients. The intervention physicians achieved a 35.5 % (49.6 SD) reduction with the first group of patients and a 50.6% (35.3 SD) with the second group of patients post-intervention.

Health service outcome: Rate of readmission to hospital

The long-term follow up cited in Hamann's 2007 paper investigated rehospitalization rates 6 months and 18 months after discharge. The authors found no difference between the control and intervention groups on rates of hospital readmission.

Primary outcome data

The primary outcome data for these studies are provided in Table 1; Table 2; Table 3. In neither study were the intervention and control groups matched at baseline. Both studies controlled for this statistically, one using ANCOVA and the other a general linear model. For this reason the outcome data for each study are presented separately in tables as the group means are not directly comparable within studies.

Secondary outcomes

Level of consumer involvement in the decision-making process

Only Loh 2007a measured this outcome. Significantly higher patient participation was found in the intervention group using the Patient's Perceived Involvement in Care Scale - doctor facilitation (PICS-DF) (group x time interaction P = 0.028) (Lerman 1990). When measured using the the Man-Song-Hing scale (group x time interaction) the result was not significant (P = 0.622). Neither was it found to be statistically significant when measured by the Patient Involvement in Care Scale - information seeking (PICS-IS), P = 0.332).

Consumer satisfaction with information provided

This outcome was not measured explicitly. The COMRADE composite measures provides some indication of satisfaction with information but cannot be further dissected.

Consumer knowledge

Hamann 2006 measured knowledge before discharge using an unvalidated questionnaire with 7 multiple-choice questions. Patients' knowledge in the intervention group as measured by this scale had improved at discharge (P = 0.01).

Provider satisfaction

In Hamann 2006 the difference in intervention group psychiatrist satisfaction before discharge was statistically significant (P = 0.02).

Consumer concordance with treatment plan

Whilst neither study directly measured concordance, both studies measured conceptually similar outcomes and in neither was the result statistically significant. The Hamann 2006 study followed patients treatment compliance over the longer term. No significant effects on secondary outcomes were found up to two years after discharge. In particular both studies measured patient compliance with treatment plan and neither found significant effects of the intervention. However treatment compliance is a difficult outcome to measure. Hamann used a composite measure consisting of the MARS questionnaire, doctor rating of compliance on a 4-point scale, and plasma levels of antipsychotics to create a dichotomous outcome measure. Loh 2007a used two separate treatment adherence outcome measures at 6 to 8 weeks post intervention: a doctor rating of compliance and a patient rating. Both were a Likert scale based on a single question. It is possible that neither of these methods adequately capture the complexity of compliance behaviour, in the Hamann case because a lot of information is lost when it is collapsed into a dichotomous variable and in the Loh case because a single question of how compliant a person is may not be reliable.

Consultation time

Both studies found that an intervention to increase the level of SDM did not lead to an increase in consultation times in the intervention group.

Other service outcomes

As reported above, Loh 2007a found significant intervention effects on doctor facilitation of patient participation in the decision making process. Hamann 2006 did not specifically measure patient involvement in decision making but did use an indicator of decision effectiveness from the patient's perspective (COMRADE). Hamann 2006 found that intervention group patients had greater knowledge about their disorder at discharge, but found no differences between groups in perceived involvement at discharge.

No mention of harms of the interventions were made in either study.

Outcomes not measured

The following secondary outcomes identified in the protocol for this review (Duncan 2008) were not measured in either study:

- Consumer satisfaction with decision;
- Consumer experience of patient-provider interaction;
- Consumer quality of life;
- Provider knowledge;
- Family/carer satisfaction;
- Family/carer experience of family/carer-provider interaction;
- Family/carer involvement in the decision-making process;
- Intent to change health behaviour.

DISCUSSION

Summary of main results

Two studies, undertaken in the inpatient treatment of schizophrenia (Hamann 2006) and the treatment of newly diagnosed depression in primary care (Loh 2007a), were included in this review. The two included studies were both conducted well and their limitations reflect constraints on all research in this area. These include baseline comparability of groups drawn from a limited pool of potential participants, loss to follow up, and self-selection of participating physicians. As is often the case in psychiatric research, there were high levels (around 30%) of loss to follow up of patients in both studies. The investigators indicate that a single 'dose' of the intervention may not be enough to gain long-term effects. Repeated administration of the decision aid and regular training refreshers may be necessary to sustain change. They also found that participants who wanted more involvement in treatment decisions were more likely to be readmitted to hospital during follow up.

As research in this area is at a comparatively early stage both these studies had a role in establishing the feasibility of providing these interventions. An important consideration in decision making in mental health is the patient's capacity to participate. Although the inclusion criteria were very broad in Hamann 2006, 31 patients were still excluded on the grounds that the physicians deemed they were too ill to participate in the decision making process. Inpatients were eligible for recruitment to the study if their score on the conceptual disorganisation scale of the PANSS was less than 5. The authors investigated the relationship between measures of psychiatric symptoms and psychiatrist's ratings of decision making capability in those who participated in the study. The patients that did participate and were rated by their physicians as capable of making a decision were less likely to have negative symptoms (eg. apathy, social withdrawal) than those rated as not capable. These results indicate that it is lack of interest or motivation to take part in the decision making process that is the issue rather than overall levels of mental health. The investigators comment that this finding is compatible with the application of shared decision making (SDM) in acute psychiatry, as patients who are not interested in sharing the decision are not obliged to.These studies also established that the intervention to Increase SDM did not lead to increase in consultation times.These studies have confirmed that SDM is possible for these groups and that it does not take up additional time compared to treatment as usual.

Primary Outcomes

Regarding the primary outcomes for this review, Loh 2007a found that patients in the SDM intervention group were more satisfied with their care than patients in the control group. However, Hamann 2006 found no difference between groups in terms of overall satisfaction with care. The measure of satisfaction used in these studies (the ZUF-8) reflects patients' global satisfaction with their care. That is, it is not restricted to the interaction with their practitioner that was the object of the SDM intervention.This may partly explain the difference in findings between studies. In the Loh study the participants were outpatients and the interaction with their physician was probably their only healthcare experience. However, in the Hamann study, the inpatients would have had multiple contacts with health professionals during their treatment. In an inpatient environment, one shared decision may be incongruent with the rest of the patient's experience. Different study designs are required for different settings and decision making contexts. For example, in inpatient settings all members of a team may need to be trained in the principles of SDM. Alternatively, in circumstances where a single decision is the object of the intervention within ongoing inpatient care, using more specific measures of satisfaction that measure satisfaction with the decision itself (e.g. Sainfort 2000; Wills 2003) may also help to isolate the effects of the intervention .

Neither study found evidence of an effect on clinical outcomes. In the Loh 2007a study, the intervention physicians were already achieving high levels of symptom reduction (patients on average mildly depressed after 6 to 8 weeks of treatment) so there may be a ceiling effect whereby these physicians could not achieve better results within this time frame. Even were this not the case, given the length of time for some antidepressant medications and talking therapies to take effect, 6 to 8 weeks may be too short a period to see the maximum treatment effects. This is assuming that SDM affects outcomes via a pathway involving optimum selection of treatment from the patient's perspective (people who want talking therapies get them and/or patients get antidepressants with a side-effect profile they find tolerable) which then affects treatment adherence and hence improves treatment outcome. If SDM is hypothesised to directly affect outcome via a 'doctor as drug' process—that is, being included in the treatment decision making and having interaction with a health professional who values the patient as a human being, is therapeutic in itself—then the effect would be more immediate. This second model has some plausibility in the primary care treatment of mild depression.

The pathways by which SDM has been conjectured to affect clinical outcomes are complex. For example, if for a SDM intervention to effect clinical outcomes requires:

- a significant proportion of patients desire a higher level of involvement in decision making,
- that the physician has the skills to facilitate this (that the intervention is effective at this level),
- that this results in a 'better' choice of treatment for the majority of patients,
- that this results in a higher degree of patient adherence to the treatment plan,
- which in turn results in a measurable improvement in outcome;

any link in this chain being broken will result in no effect on treatment outcomes.

In the treatment of long-term mental health problems, a particularly weak link in this chain is arriving at the optimum treatment choice at the first attempt. It may be that a single patient-physician encounter at which SDM is employed is inadequate to effect a change with regard to clinical outcomes. Anecdotal description of the treatment of chronic disorders suggests that regular review of medications is necessary, and trial and error to find the best treatment regimen is to be expected. As suggested by Montori, an on-going partnership between the patient and the clinical team may be necessary for SDM to be fully implemented (Montori 2006). It is clear that the research design necessary to test effects of SDM in long-term relationships will be different to that for isolated decisions. This highlights the need to develop a distinctive evidence base for the effects of SDM in one-off clinical encounters versus SDM in an ongoing therapeutic relationship where the process of SDM may be developed over time as part of the process of recovery. There is at present a lack of good quality research evidence about the long-term effects of SDM interventions in mental health conditions in either context.

Another factor to consider in conducting long-term studies is that although training may lead to short-term changes in behaviour, making permanent changes to physician and patient behaviour may need repeated training interventions. Observational studies have demonstrated that most physicians do not routinely practice SDM (Goossensen 2007; Young 2008). It is plausible that to effect long-term change to established patterns of behaviour would be difficult (Ponte 2003). Although the Hamann study did involve follow up over 18 months post discharge, there was only a single intervention. One would suspect that patients who have had previous admissions and a long history of psychiatric treatment would take time to establish that the mode of decision making had changed and to engage with the process. This is a particular risk for SDM in mental health contexts as these patients are more likely to have experienced involuntary treatment which may affect their ability to trust health professionals. There is however, evidence that mental health patients want to participate in healthcare decisions and to have more information about their illness and potential treatments (Adams 2007; Garfield 2004; Hamann 2005). There is also evidence that patients, particularly those treated involuntarily, do not currently feel involved in decisions and would have chosen different treatments had they been involved in the decision making process (Hamann 2008). Even pushing at an open door, established patterns of behaviour and modes of relating may take time and effort to change.

Whilst the lack of a sufficient number of high quality studies makes drawing firm conclusions impossible, two null results on the effect of SDM interventions on clinical outcomes suggests that SDM does not not have a large effect on clinical outcomes. Some commentators have questioned whether clinical outcomes are an appropriate outcome measure for SDM interventions. That is, why should SDM interventions affect clinical outcomes at all? Some argue that it is enough for SDM interventions to change the nature of the physician-patient interaction and they should not be expected to influence 'hard' biological outcomes even by the tortuous routes outlined above.

Hospital readmission rates were examined in Hamann 2006, and no evidence of effect was found. The long-term follow up of the patients in the Hamann study found an indication that patients with higher participation preferences had a trend towards higher levels of hospital readmission. This may indicate that when some patients are truly involved in treatment decisions, the resulting decisions may have greater risks associated with them than if the practitioner were to decide alone. The user-led recovery movement acknowledges that the recovery process entails some responsible risk taking. Anecdotal evidence supports the conclusion that such a process can lead to improved therapeutic alliance and good outcomes (Deegan 2007; Tyrer 2000). Another interpretation of this finding is that these patients are using appropriate help-seeking behaviour. It would require further long-term follow up and qualitative investigation to determine whether this is the case.

Secondary outcomes

There was an indication that interventions to increase SDM enhance doctor facilitation of patient involvement in decision making and increase patient knowledge of their disorder. It was also found that the included interventions to increase SDM did not increase consultation times, or patient compliance with treatment plan.

Overall completeness and applicability of evidence

The most important finding from this review is that there are very few experimental studies examining the effects of SDM interventions for people with mental health conditions. Further research is urgently needed in this area, particularly in light of the fact that clinical guidelines and health policies are already advocating the use of SDM in advance of evidence of positive effect (National Prescribing Centre 2007; NICE 2007).

It should be noted that the development of the decision support material in both Hamann 2006 and Loh 2007a occurred before the publication of the IPDAS criteria (Elwyn 2006), the now available consensus criteria for the development of decision support tools. The use of these criteria in future studies will help to standardise the content and ensure rigorous development and testing processes for decision tools across clinical conditions.

Quality of the evidence

Although on the face of it there was a high risk of bias in the studies due to unconcealed allocation to groups, lack of blinding, and so on, the context of the challenging research environment must not be forgotten. The investigators should be commended for their efforts to conduct controlled trials in this field.

Potential biases in the review process

A potential bias for reviews in this field is employing a clear criteria for what constitutes an intervention to increase SDM. Although we have endeavoured to provide a clear definition based on Charles' criteria (Charles 1997), and have been greatly assisted in this by the standard procedures for conducting a Cochrane review, this is still open to some interpretation. This is particularly the case as we have stipulated that we would include studies that addressed two or more aspects of Charles' criteria. Other work in this field has identified that definitions are used inconsistently by investigators (Makoul 2005).

To illustrate the difficulty of defining SDM interventions, in the excluded study by Ludman (Ludman 2003) the investigators describe the intervention as including procedures for SDM.

However where the intervention is described in more detail it is described as motivational interviewing with the goal of increasing uptake of psychoactive medication. Motivational interviewing involves making the patient aware of the discrepancy between their behaviours and what they want from life (Miller 2002). SDM requires decisional equipoise, that is, a range of possible treatment options and where the process of deciding between these can be informed by the preferences and values of patient and provider.

There is some evidence from other qualitative research on SDM that although practitioners are making efforts to engage patients in the decision making process sometimes the practitioner already has an end goal in view and is trying to engineer a particular outcome while appearing to give the patient a choice (psychiatry: Seale 2006; other medical settings: Silverman 1987; Watson 2008). Whilst this may be done benevolently, it highlights the importance of clear definitions of SDM. Healthcare practitioners' preferences have a legitimate place in the decision, but SDM requires that these be made explicit. This is of relevance to this review because further research in the field of SDM requires clear and consistent definitions of SDM as discussed by Moumjid 2007. The decision making context is important, as SDM research must be in areas in which SDM is theoretically appropriate; that is, where there is decisional equipoise (Elwyn 2006).

Agreements and disagreements with other studies or reviews

This review has not found any evidence that SDM improves health outcomes. This is in contrast to literature from outside the scope of this review. For example, Clever 2006 in a prospective cohort design found that patients who rated themselves as having been involved in decisions about their healthcare were more likely to have an improvement in their depression over 18 months. This was an observational study based on data from the Quality Improvement in Depression program. Apart from the study design itself, one possible explanation for the discrepancy in results is that SDM is only beneficial to the patients who want a higher degree of involvement in decision making. Where both patient and practitioner are naturally inclined to share the decision, this leads to better outcomes. However this also brings challenges, as there is some indication that practitioners find it hard to identify patients who would like to participate in SDM (Edwards 2005), and some patients often do not know what it means to be involved until this has been explained to them. This explanation of the decision making circumstances and potential modes of engagement is one of the tasks of the SDM process (Elwyn 1999). However, in environments where large proportions of patients then choose not to participate, the cost effectiveness of interventions to increase SDM will be limited. Furthermore, achieving differences in health outcomes requires a complete chain of events to occur in sequence; from the professional being trained correctly in delivering SDM interventions, to having patients who are willing and able to participate in SDM, and the delivery of an effective intervention that manages to change clinical outcome. Given this series of steps, it is perhaps unsurprising that improvements in health outcomes were not identifiable in the included studies. Such methodological difficulties have also been reported elsewhere (Kinnersley 2007).

The results of this review differ from those of other recent reviews in this area. The review by Joosten 2008 included studies from all medical specialities. The two mental health studies they included were both excluded from this review. This is because they were complex interventions compared to treatment as usual and it is not possible to determine to what extent the outcomes are influenced by the SDM aspect of the intervention. The review by Hamann 2003 was published five years ago, and its study design inclusion criteria was much broader than for this review. There were four included studies in the Hamann 2003 review. None of these studies met inclusion criteria for this review. One exclusion was on methodological grounds: Bunn 1997 had no control condition. The other three studies included in Hamann 2003 did not meet our criteria on the basis that they did not focus on increasing the amount of SDM. Instead they focused on the influence of patient treatment preferences on treatment outcomes. The results of these reviews concur in that they state that there is a need for more research into SDM for mental health conditions.

Health professionals are being urged to incorporate procedures for SDM into their practice. For example the NICE guideline for treatment of anxiety states that "shared decision-making between the individual and the health professionals should take place during the process of diagnosis and in all phases of care" (NICE 2007). The National Prescribing Centre has developed a competency framework for health professionals to share decisions about medication prescribing (National Prescribing Centre 2007). The incorporation of SDM protocols into medical practice is underway. The ethical motivation for this movement is clearly articulated, as is the assumption that patients will adhere more closely to treatment plans they have been involved in creating. However empirical evidence on the effects of SDM interventions for people with mental health conditions is still largely lacking.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient research evidence to suggest changes to practice. The evidence from this review suggests that interventions to increase SDM in patients with mental health conditions do not improve health outcomes but they may increase patient satisfaction, without an increase in consultation times or use of health services resources. There is no evidence of harm. Given the ethical arguments in support of SDM, we would recommend that practitioners continue to try to engage patients collaboratively in the treatment decision making process.

Implications for research

The issues to be considered when designing further research into SDM for mental health conditions can be categorised as: 1) appropriate contexts for SDM, and 2) factors moderating the effectiveness of SDM interventions.

1) There are a number of factors that may contribute to whether SDM is appropriate for a decision. It is not theoretically appropriate to conduct research into SDM unless these conditions are met. We suggest that these are:

- Whether all participants/observers can agree that there is a particular decision to be made (Hamann 2008); an identified decision, as opposed to general 'treatment planning';
- Capacity of patients to undertake SDM;
- Availability of treatment options; and
- Decisional equipoise.

2) There are also factors (clearly interlinked) that may moderate the effects of SDM interventions:

- Type of decision: one off irreversible versus reversible component of ongoing treatment;
- Type of relationship between practitioner and patient: new and temporary versus established and likely to continue (noting that a patient may be in ongoing treatment without continuity of provider);
- Type of illness: chronic versus acute, mild versus life threatening;
- Practitioner skills in applying SDM techniques (Joosten 2008), fidelity of intervention - implies necessity of measuring the extent of SDM that takes place (OPTION scale);
- Practitioner traits (Chapman 2008);
- Traits of the patient (anxiety traits (Graugaard 2000); external locus of control (Schneider 2006); age, education, gender); and
- Accuracy of the practitioner's implicit judgements about whether a patient wants to be involved in the decision (Elwyn 2000; Goossensen 2007).

To explore fully the effectiveness of SDM interventions for mental health conditions, further research would need:

1. to be conducted in contexts that are suitable for SDM, as well as
2. to examine intervention effectiveness under the influence of the factors identified above.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Hamann 2006

Methods	Cluster randomised controlled trial (unit of randomisation = ward).
Participants	Inpatients with ICD-10 diagnosis of schizophrenia or schizophreniform disorder (F20/F23). Mean age intervention group: 35.5 yrs (SD 11.9); mean age control 39.6 years (SD 10.8). Intervention group 41% female, control group 53% female.
Interventions	Patients - Decision aid - 16 page booklet. Patients were assisted in working through this by nurses. Duration 30 to 60 minutes. Patients met with their physicians within 24 hours afterwards for a planning talk. Nurses - instructed on use of decision aids. Physicians - two information sessions on SDM and the required communication skills.
Outcomes	*Physician rated:* Psychopathology: Positive and Negative Syndrome Scale for Schizophrenia (PANSS - validated, Kay 1987) (Baseline and at discharge). Global functioning (GAF, validated APA 2000) and severity of illness (Clinical Global Impressions Scale, validated Guy 1976) (6 and 18 months after discharge Rating of time spent per week with patient (at discharge).

Hamann 2006 *(Continued)*

	Rehospitalization (6 and 18 months after discharge - dichotomous outcome) Provider satisfaction (unvalidated 5 point rating scale at point of discharge) *Patient rated:* Patient satisfaction (ZUF-8, German version of the CSQ - validated, Schmidt 1989) (at discharge). Risk communication and confidence in decision (COMRADE - validated, Edwards 1999) (immediately after the intervention and at discharge). Patient knowledge (unvalidated questionnaire, at discharge). *Composite measure:* Patient concordance with treatment plan -dichotomous outcome (based on patient completion of MARS questionnaire, patient compliance as rated by the physician on a 4-point scale, and plasma levels of antipsychotics) rated at 6 and 18 months post discharge.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	High risk	Sequence generation took place after wards had been paired based on their characteristics so this is not truly random.
Allocation concealment?	High risk	Randomisation was at the ward level. Adequate allocation concealment at the level of the patient would not be possible.
Blinding? All outcomes	Unclear risk	Participants, providers, outcome assessors were not blinded, unclear whether data analysts were blinded.
Incomplete outcome data addressed? All outcomes	High risk	Significant loss to follow up

Loh 2007a

Methods	Cluster randomised controlled trial (unit of randomisation = physician).
Participants	Primary care patients newly diagnosed with depression (PHQ). Around two thirds of the participants were female. The average age of the control group was around 41 years (SD 13) and the average age of the intervention group was around 49 years (SD 17)
Interventions	Patient - Decision board for use during consultation that was handed out to the patients to take away. Printed patient information that combined evidence-based knowledge about depression care with specific encouragement for patients to be active in the decision-making process. Physician - Modules on guideline concordant depression care. Enhancing skills for involving patients in the decision making process. Facilitation practice, role playing and video examples of high quality decision making. Standardized case vignettes. 5 scheduled training events over a 6 month period.
Outcomes	Patient participation doctor facilitation (PICS-DF, validated Lerman 1990). Patient participation information seeking (PICS-IS, validated Lerman 1990). Patient participation Man-Song-Hing Scale (Man-Song-Hing 1999).

Loh 2007a *(Continued)*

	Consultation time. Levels of Depression (measured by PHQ 9 Spitzer 1999). Patient satisfaction (ZUF-8 German version of the CSQ - validated, Schmidt 1989). Patient assessment of treatment adherence (1 question on a 5-point Likert scale). Physician assessment of treatment adherence (1 question on a 5-point Likert scale).
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Physicians drew blinded lots.
Allocation concealment?	Unclear risk	Randomisation was at physician level. Adequate allocation concealment at the level of the patient would not be possible for new patients, acceptable for existing patients.
Blinding? All outcomes	High risk	Providers were not blinded, participants were blind and outcome assessors and data analysts were not blind (this information was provided by the investigators).
Incomplete outcome data addressed? All outcomes	High risk	Significant loss to follow up.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Bauer 2006	Complex intervention to address what the authors termed collaborative care for bipolar disorder. Intervention consisted of three components: 1) Group psychoeducation in the first months of treatment; 2) Development of simplified clinical practice guidelines to produce an algorithm to guide pharmacological treatment and; 3) system reorganisation to ensure access to and continuity of care including scheduled care, demand responsive care, and outreach and inreach contacts to proactively follow-up missed appointments and liaise with other service providers.
Bedi 2000	Patient preference trial.
Bieber 2008	Not mental health - fibromyalgia.
Bunn 1997	No control group.
Chapman 2008	Observational study.
Clever 2006	Observational study.
Day 2005	Observational study.
Eisen 2000	Information exchange is uni-directional and not concerning a specific decision.

Study	Reason for exclusion
Eisenthal 1979	Observational study.
Goossensen 2007	Observational study.
Graugaard 2000	Participants were not diagnosed with a mental health condition by DSM/ICD criteria.
LaFerriere 1978	Client and therapist jointly agree and document goals of psychotherapy - part of psychotherapy process rather than SDM.
Little 2004	Participants not all diagnosed with mental health condition.
Ludman 2003	Complex intervention to deliver brief primary care-based relapse prevention. Intervention consisted of four components: 1) an educational book and videotape about effective management of chronic or recurrent depression; 2) Two visits from a depression prevention specialist in the primary care clinic; 3) Three scheduled telephone monitoring contacts; and four mailings to the individual to enable continued monitoring and treatment adherence.
Maas 2004	Not SDM.
Malm 2003	Complex intervention. Intervention consisted of integrated mental health care: a combination of anti-psychotic drug treatment, psycho-educational family intervention, living skills training together with a social network resource for SDM, structured communication training and structured problem solving training.
Schneider 2006	Observational study.
Startup 2006	Observational study.
Swanson 2007	Observational study.
Von Korff 2003	Complex intervention to deliver brief primary care-based relapse prevention. Intervention was the same as delivered by Ludman 2003.
Wong 2007	Study to determine whether certain communication skills could be taught. No outcome measures apart from communication behaviours.
Young 2008	Observational study.

ADDITIONAL TABLES

Table 1. Hamann 2006 Outcome Data

Outcome measure	Intervention (Standard Deviation (SD))	Control (SD)	F	d.f.	P value
Knowledge before discharge	15.0 (4.4)	10.9 (5.4)	6.65	1	0.01
Patient satisfaction scale before discharge (ZUF-8)	16.3 (3.7)	16.4 (3.2)	0.66	1	0.42

Table 1. Hamann 2006 Outcome Data *(Continued)*

Clinical outcome PANSS	58.0	59.3	> 0.05
Time spent in individual contacts with psychiatrist (min/week)	64	60	> 0.05

Group differences were analysed using a general linear model with patients' age, PANSS positive score at study entry, patients' knowledge and route of admission as covariates (time from admission to study entry was used as an additional covariate for the first measurement of COMRADE). Standard deviation for PANSS and 'time spent' are not given in the original paper.

Table 2. Loh 2007a Outcome Data

Outcome measure	ICC	Control Pre (Standard Deviation (SD))	Control Post (SD)	Intervention Pre (SD)	Intervention Post	Main effect group (P value)	Main effect time (P value)	Group X time (P value)
Patient involvement in decision making - Doctor facilitation (PICS-DF)	0.087	14.7 (3.7)	14.5 (3.3)	15.4 (3.5)	17.4 (3.1)	0.005	0.003	0.028
Patient involvement in decision making Information seeking (PICS-IS)	0.110	11.3 (2.9)	10.3 (2.9)	12.3 (2.7)	12.3 (3.4)	0.015	0.364	0.332
Patient Participation (Man-Song-Hing) Scale	0.136	24.5 (3.7)	25.5 (3.0)	26.3 (4.0)	28.0 (2.9)	0.003	0.010	0.622
Patient satisfaction	0.174	n.d.	27.0 (3.6)	n.d.	29.8 (2.7)	0.014	n.c.	n.c.
Consultation time	0.563	30.9 (25.4)	26.7 (12.5)	31.4 (15.1)	29.2 (10.7)	0.681	0.359	0.758
Depressive symptom severity reduction	0.345	12.4 (47.8)	45.9 (34.2)	35.5 (49.6)	50.6 (35.3)	0.236	0.031	0.387
Patient assessment of adherence	0.105	3.9 (0.8)	3.9 (1.0)	4.3 (0.8)	4.3 (0.9)	0.073	0.810	0.784
Physician assessment of adherence	0.389	4.2 (1.1)	4.3 (1.1)	4.3 (0.9)	4.8 (0.6)	0.560	0.215	0.476

Data were analysed with ANCOVA with adjustment for clustering effect. All variables that were associated with group assignment or measurement point were controlled for.

Table 3. Hamann 2007 outcome data

Outcome measure	Intervention	Control	P value
Patients hospitalised within 6 months, N/N (%)	8/36 (22)	8/37 (22)	> 0.05
Patients hospitalised within 18 months, N/N (%)	20/38 (53)	19/41 (46)	> 0.05
CGI score at 18 months, mean (SD)	4.0 (1.5)	4.1 (1.4)	> 0.05
GAF score at 18 months, mean (SD)	54.7 (16.5)	51.0 (18.5)	> 0.05
Patient good compliance at 6 months N/N (%)	16/39 (41.0)	26/47 (55.3)	> 0.05
Patient good compliance at 18 months N/N (%)	18/30 (60.0)	22/38 (57.9)	> 0.05

Number of patient hospitalised was analysed with a Chi^2 test and the CGI and GAF scores with a t test.

APPENDICES

Appendix 1. MEDLINE (Ovid) search strategy

Study design filter
1. randomized controlled trial.pt. 267685

2. controlled clinical trial.pt. 80495

3. random allocation.sh. 63343

4. double blind method.sh. 101117

5. single blind method.sh. 12666

6. or/1-5 402543

7. (animals not humans).sh. 3279216

8. 6 not 7 373572

9. clinical trial.pt. 459906

10. clinical trials.mp. 216506

11. (clin$ adj25 trial$).ti,ab. 154328

12. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).ti,ab. 98834

13. random$.ti,ab. 431494

14. or/9-13 876907

15. 14 not 7 816492

16. 15 not 8 471831

17. Comparative study.sh. 1441389

18. exp Evaluation studies/ 112453

19. Follow-up studies.sh. 382918

20. Prospective studies.sh. 255626

21. (latin adj square).tw. or cross-over studies.sh. 25712

22. or/17-21 2007869

23. 22 not 7 1628692

24. 23 not (8 or 16) 1339030

25. 8 or 16 or 24 2184433

Mental health conditions filter

26. exp Eating disorders/ 17323

27. exp Anorexia nervosa/ 9033

28. exp Bulimia/ 4411

29. exp Suicide, attempted/ 11784

30. exp Self mutilation/ 2764

31. exp Self-injurious behavior/ 42735

32. exp Mood disorders/ 87773

33. exp Bipolar disorder/ 24741

34. exp Neurotic disorder/ 15094

35. exp Depressive disorder/ 61675

36. exp Dysthymic disorder/ 735

37. exp depression/ or exp depression, involutional/ or depression, post partum/ 63611

38. exp Seasonal affective disorder/ 1013

39. exp anxiety/ or exp anxiety disorders/ or exp anxiety, separation/ or exp dental anxiety/ 86637

40. exp panic/ or exp panic disorder/ 7149

41. exp phobic disorders/ 7566

42. exp combat disorders/ or exp stress disorders, post-traumatic/ 14309

43. exp Somatoform disorders/ 10685

44. exp Hypochondriasis/ 1940

45. exp Hysteria/ 3246

46. exp Conversion disorder/ 1618

47. exp munchausen syndrome/ or munchausen syndrome by proxy/ 1557

48. exp Neurasthenia/ 1262

49. exp Fatigue syndrome, chronic/ 3338

50. exp Obsessive-compulsive disorder/ 8903

51. exp Obsessive behavior/ 645

52. exp Compulsive behavior/ 4056

53. exp Stress, psychological/ 65085

54. *Mental Disorders/ 73587

55. or/26-54 392034

56. exp schizophrenia/ 70642

57. exp paranoid disorders/ 3543

58. schizo$.mp. 101093

59. hebephreni$.mp. 257

60. oligophreni$.mp. 857

61. psychotic$.mp. 38103

62. psychos#s.mp. 26379

63. (chronic$ adj mental$).ti,ab. 1429

64. (sever$ adj mental).ti,ab. 3928

65. (mental$ adj disorder$).ti,ab. 14076

66. (mental$ adj ill$).ti,ab. 15407

67. (emotion$ adj disorder$).ti,ab. 1200

68. or/56-67 162164

69. 68 or 55 502215

Shared decision making filter

70. decision making.sh. 48466

71. exp choice behavior/ 25333

72. (share$ adj decision adj mak$).ti,ab. 861

73. (decision adj analys$).mp. 2623

74. or/70-73 74810

75. (patient or client or subject or person or consumer).mp. 1500334

76. (family or carer).mp. 507693

77. (professional or physician or clinician or practitioner).mp. 324560

78. (75 and 77) or (76 and 77) 165821

79. professional-patient relations.sh. 16367

80. physician-patient relations.mp. 48821

81. or/78-80 165821

82. (shar$ adj information).mp. 629

83. (patient adj choice$).mp. 651

84. (patient adj understanding).mp. 313

85. ((check or clarify) adj3 understanding).mp. 142

86. physician preferences.mp. 92

87. (treatment adj options).mp. 16969

88. values.mp. 637116

89. preferenc$.mp. 61120

90. (communicat$ adj risk).mp. 135

91. attitude of health personnel.sh. 69460

92. (patient adj expect$).mp. 778

93. (problem adj definite$).mp. 113

94. (ask adj question$).mp. 431

95. (assess adj risk).mp. 934

96. self-manag$.mp. 3873

97. equipoise.mp. 258

98. or/82-97 784196

99. (decision adj aids).mp. 341

100. decision support techniques.sh. 7169

101. checklist.mp. 9900

102. or/99-101 17264

103. (goal adj set$).mp. 1002

104. negotiat$.mp. 8821

105. deliberat$.mp. 7882

106. (decis$ and mak$).mp. 98055

107. consensus.mp. 72732

108. concordance.mp. 15748

109. agreement.mp. 102611

110. (action adj plan).mp. 1151

111. or/103-110 296646

112. 'quality of life'.tw. 75443

113. (patient adj satisfaction).mp. 43055

114. (follow adj up).mp. 624838

115. readmission.mp. 7336

116. (treatment adj (compliance or concordance)).mp. 994

117. or/112-116 723832

118. (74 and 81) or (81 and 98) or (81 and 102) or (81 and 111) or (74 and 117) or (98 and 117) 80709

119. 25 and 69 and 118 2099

Appendix 2. EMBASE search strategy

1. clinical trial/ 521329

2. randomised controlled trial/ 163962

3. random allocation.tw. 632

4. double blind method.tw. 201

5. single blind method.tw. 40

6. or/1-5 523987

7. animal experiments.sh. 1262808

8. 6 not 7 520954

9. (clin$ adj25 trial$).ti,ab. 143322

10. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).ti,ab. 93045

11. random$.ti,ab. 383693

12. Comparative study.tw. 29347

13. Evaluation studies.tw. 740

14. Follow-up studies.tw. 5558

15. Prospective studies.tw. 11435

16. ((latin adj square) or cross-over studies).tw. 1288

17. or/9-16 549056

18. 17 not 7 508754

19. 8 or 18 811640

20. exp Eating disorders/ 17089

21. exp Anorexia nervosa/ 8143

22. exp Bulimia/ 6834

23. exp Suicide, attempted/ 8628

24. exp Self mutilation/ 4625

25. exp Self-injurious behavior/ 4625

26. exp Mood disorders/ 166656

27. exp Bipolar disorder/ 18154

28. exp Neurotic disorder/ 30958

29. exp Depressive disorder/ 151404

30. exp Dysthymic disorder/ 3150

31. exp depression/ or exp depression, involutional/ or depression, post partum/ 151404

32. exp Seasonal affective disorder/ 330

33. exp anxiety/ or exp anxiety disorders/ or exp anxiety, separation/ or exp dental anxiety/ 107091

34. exp panic/ or exp panic disorder/ 10768

35. exp phobic disorders/ 10933

36. exp combat disorders/ or exp stress disorders, post-traumatic/ 13997

37. exp Somatoform disorders/ 7195

38. exp Hypochondriasis/ 1628

39. exp Hysteria/ 2725

40. exp Conversion disorder/ 394

41. exp munchausen syndrome/ or munchausen syndrome by proxy/ 1078

42. exp Neurasthenia/ 427

43. exp Fatigue syndrome, chronic/ 4054

44. exp Obsessive-compulsive disorder/ 13388

45. exp Obsessive behavior/ 6623

46. exp Compulsive behavior/ 4246

47. exp Stress, psychological/ 12030

48. *Mental Disorders/ 29051

49. or/20-48 290905

50. exp schizophrenia/ 62162

51. exp paranoid disorders/ 5509

52. schizo$.mp. 77006

53. hebephreni$.mp. 302

54. oligophreni$.mp. 360

55. psychotic$.mp. 16046

56. psychos#s.mp. 42889

57. (chronic$ adj mental$).ti,ab. 943

58. (sever$ adj mental).ti,ab. 3554

59. (mental$ adj disorder$).ti,ab. 11800

60. (mental$ adj ill$).ti,ab. 11610

61. (emotion$ adj disorder$).ti,ab. 991

62. or/50-6 1128025

63. 62 or 49 368414

64. decision making.sh. 41642

65. exp choice behavior/ 41642

66. (share$ adj decision adj mak$).ti,ab. 737

67. (decision adj analys$).mp. 2425

68. or/64-67 43969

69. (patient or client or subject or person or consumer).mp. 1321523

70. (family or carer).mp. 344913

71. (professional or physician or clinician or practitioner).mp. 229287

72. (69 and 71) or (70 and 71) 105778

73. professional-patient relations.sh. 13951

74. physician-patient relations.mp. 19

75. or/72-74 118531

76. (shar$ adj information).mp. 391

77. (patient adj choice$).mp. 509

78. (patient adj understanding).mp. 239

79. ((check or clarify) adj3 understanding).mp. 116

80. physician preferences.mp. 77

81. (treatment adj options).mp. 16360

82. values.mp. 444610

83. preferenc$.mp. 49124

84. (communicat$ adj risk).mp. 126

85. attitude of health personnel.sh. 1800

86. (patient adj expect$).mp. 642

87. (problem adj definite$).mp. 110

88. (ask adj question$).mp. 311

89. (assess adj risk).mp. 819

90. self-manag$.mp. 3110

91. equipoise.mp. 232

92. or/76-91 514437

93. (decision adj aids).mp. 323

94. decision support techniques.sh. 1480

95. checklist.mp. 9291

96. or/93-95 11046

97. (goal adj set$).mp. 687

98. negotiat$.mp. 4085

99. deliberat$.mp. 6482

100. (decis$ and mak$).mp. 109904

101. consensus.mp. 59338

102. concordance.mp. 13966

103. agreement.mp. 91958

104. (action adj plan).mp. 878

105. or/97-104 277058

106. 'quality of life'.tw. 69849

107. (patient adj satisfaction).mp. 36424

108. (follow adj up).mp. 441380

109. readmission.mp. 4648

110. (treatment adj (compliance or concordance)).mp. 978

111. or/106-110 529991

112. (68 and 75) or (75 and 92) or (75 and 96) or (75 and 105) or (68 and 111) or (92 and 111) 52777

113. 19 and 63 and 112 1117

Appendix 3. PsycINFO (Ovid) search strategy

1. "2000".md. 13409

2. "1200".md. 6412

3. "0600".md. 901

4. "0400".md. 1098742

5. "0200".md. 43294

6. or/1-5 1119842

7. exp eating disorders/ 16552

8. exp anorexia nervosa/ 6634

9. exp bulimia/ 5532

10. exp suicide, attempted/ 5970

11. exp self mutilation/ 942

12. exp self-injurious behavior/ 1865

13. exp Mood disorders/ 80306

14. exp Bipolar disorder/ 12607

15. exp affective disorder/ 80306

16. exp major depression/ 61405

17. exp dysthymic disorder/ 1237

18. exp neurosis/ 6860

19. exp seasonal affective disorder/ 770

20. exp anxiety disorder/ 42140

21. exp panic disorder/ 5742

22. exp phobias/ 8740

23. exp posttraumatic stress disorder/ 13081

24. exp somatoform disorders/ 8743

25. exp Hypochondriasis/ 876

26. exp hysteria/ 1588

27. exp conversion disorder/ 862

28. exp munchausen syndrome/ or munchausen by proxy.mp. 183

29. exp Neurasthenia/ 218

30. exp chronic fatigue syndrome/ 1056

31. exp Obsessive-compulsive disorder/ 6976

32. exp psychological stress/ 5942

33. *Mental Disorders/ 37734

34. exp schizophrenia/ 54498

35. exp "Paranoia (Psychosis)"/ 1176

36. schizo$.mp. 79424

37. hebephreni$.mp. 497

38. oligophreni$.mp. 503

39. psychotic$.mp. 27995

40. psychos#s.mp. 38144

41. (chronic$ adj mental$).ti,ab. 1999

42. (severe adj mental).ti,ab. 3517

43. (mental$ adj disorder$).ti,ab. 27366

44. (mental$ adj ill$).ti,ab. 24472

45. (emotion$ adj disorder$).ti,ab. 1972

46. or/7-45 304459

47. exp decision making/ 38932

48. (share$ adj decis$ adj mak$).ti,ab. 451

49. choice behavior/ 9869

50. (decision adj analys$).ti,ab. 438

51. or/47-50 39259

52. exp Therapeutic Processes/ 46822

53. therapeutic alliance/ 1802

54. (professional or physician or clinician or practitioner).mp. 131212

55. (patient or client or subject or person or consumer).mp. 284788

56. (family or carer).mp. 176022

57. (54 and 55) or (54 and 56) 41767

58. (relationship or communication).mp. 365617

59. 52 or 53 or (57 and 58) 54054

60. (shar$ adj inform$).mp. 583

61. (Patient$ adj expectations).mp. 408

62. (patient$ adj understand$).mp. 431

63. ((check or clarify) adj3 underst$).mp. 145

64. ((physician or professional or practitioner or clinician) adj preference$).mp. 64

65. (treatment adj option$).mp. 2881

66. values.mp. 68174

67. preferenc$.mp. 53746

68. (communicat$ adj risk).mp. 86

69. (problem adj definite$).mp. 307

70. equipoise.mp. 50

71. exp role expectations/ 1322

72. (ask adj question$).mp. 503

73. (assess adj risk).mp. 186

74. self efficacy/ 9108

75. exp Self Determination/ or exp Self Care Skills/ 3833

76. exp Self Medication/ 341

77. or/60-75 138040

78. (decision adj aid).ti,ab. 212

79. Decision support techniques.mp. 5

80. checklist.mp. 14115

81. or/78-80 14330

82. (goal adj set$).mp. 3716

83. negotiat$.mp. 12683

84. deliberat$.mp. 6921

85. (decis$ adj mak$).mp. 47512

86. consensus.mp. 10479

87. concordance.mp. 2904

88. agreement.mp. 21724

89. (action adj plan).mp. 414

90. or/82-89 100941

91. 'quality of life'.tw. 20820

92. (patient$ adj satisf$).mp. 2078

93. (follow adj up).mp. 50161

94. readmission.mp. 1454

95. (treatment adj (compliance or concordance or adherence)).mp. 7990

96. or/91-95 79205

97. 51 and 59 771

98. 59 and 77 2802

99. 59 and 81 268

100. 59 and 90 3124

101. 51 and 96 832

102. 77 and 96 4134

103. 97 or 98 or 99 or 100 or 101 or 102 10309

104. 6 and 46 and 103 733

Appendix 4. CINAHL search strategy

1. exp Crossover Design/ 4709

2. exp Empirical Research/ 834

3. exp Experimental Studies/ 85023

4. exp Clinical Trials/ 66989

5. exp Non-experimental Studies/ 141973

6. Quantitative Studies/ 4354

7. exp Quasi-Experimental Studies/ 4302

8. Repeated Measures/ 20550

9. Retrospective Design/ 34555

10. random$.ti,ab. 59015

11. (clin$ adj5 trial$).ti,ab. 16507

12. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).ti,ab. 9085

13. (latin adj square).tw. 83

14. or/1-13 263746

15. Adjustment Disorders/ 157

16. Mental Disorders, Chronic/ 1078

17. exp Affective Disorders/ 25129

18. exp Anxiety Disorders/ 8353

19. exp Obsessive compulsive disorder/ 1159

20. Panic disorder/ 642

21. exp Phobic disorders/ 1360

22. Stress Disorders, post traumatic/ 4162

23. exp Dissociative disorders/ 334

24. exp Factitious Disorders/ 310

25. exp Somatoform Disorders/ 1031

26. exp Pregnancy Complications, Psychiatric/ 1021

27. exp Psychosexual Disorders/ 2593

28. exp Affective Disorders, Psychotic/ 2336

29. ICU Psychosis/ 82

30. exp Organic Mental Disorders, Psychotic/ 19842

31. Paranoid Disorders/ 130

32. exp Schizophrenia/ 5407

33. *Mental Disorders/ 9960

34. (chronic$ adj mental$).ti,ab. 434

35. (severe adj mental).ti,ab. 986

36. (mental$ adj disorder$).ti,ab. 2059

37. (emotion$ adj disorder$).ti,ab. 120

38. or/15-37 72246

39. decision making, clinical/ or decision making, ethical/ or decision making,

family/ or decision making, patient/ 17540

40. (choice adj behavior).ti,ab. 10

41. (share$ adj decis$ adj mak$).ti,ab. 404

42. (decision adj analys$).mp. 339

43. or/39-42 18007

44. (patient or client or subject or person or consumer).mp. 297657

45. (family or carer).mp. 73880

46. (professional or physician or clinician or practitioner).mp. 150474

47. (44 and 46) or (45 and 46) 61763

48. exp Professional-Patient Relations/ 31282

49. Researcher-Subject Relations/ 166

50. Professional-Family Relations/ 6783

51. Professional-Client Relations/ 2007

52. or/47-51 72047

53. (shar$ adj information).mp. 332

54. (patient adj choice$).mp. 356

55. (Patient$ adj understanding).mp. 278

56. ((check or clarify) adj3 understanding).mp. 26

57. physician preferences.mp. 19

58. (treatment adj option$).mp. 5497

59. values.mp. 32808

60. preferenc$.mp. 7559

61. (communicat$ adj risk).mp. 50

62. "Attitude of Health Personnel"/ 11535

63. (patient adj expect$).mp. 260

64. (problem adj definite$).mp. 29

65. (ask adj question$).mp. 215

66. (assess adj risk).mp. 177

67. self-manag$.mp. 2424

68. or/53-67 59914

69. (decision adj aids).mp. 128

70. decision support techniques.mp. 174

71. checklist.mp. 7225

72. or/69-71 7509

73. (goal adj set$).mp. 2037

74. negotiat$.mp. 4006

75. deliberat$.mp. 1483

76. (decis$ adj mak$).mp. 33961

77. consensus.mp. 6564

78. concordance.mp. 1266

79. agreement.mp. 7378

80. (action adj plan).mp. 595

81. equipoise.mp. 59

82. or/73-81 54688

83. quality of life.mp. 30447

84. (patient adj satisfaction).mp. 15392

85. (follow adj up).mp. 35362

86. (patient adj participation).mp. 346

87. (treatment adj3 compliance).mp. 633

88. or/83-87 77429

89. (43 and 52) or (52 and 68) or (52 and 72) or (52 and 82) or (43 and 88) or (88 and 68) 19482

90. 89 and 38 and 14 410

Appendix 5. British Nursing Index and Archive search strategy

1. clinical trial.af. 259

2. randomised controlled trial.af. 995

3. random allocation.af. 2

4. double blind.af. 84

5. single blind.af. 14

6. 4 or 1 or 3 or 2 or 5 1327

7. (clin$ adj25 trial$).ti,ab. 639

8. ((singl$ or doubl$ or trebl$ or tripl$) adj5 (blind$ or mask$)).ti,ab. 106

9. random$.ti,ab. 2210

10. evaluation stud$.af. 55

11. Comparative stu$.af. 278

12. Prospective stud$.af. 216

13. ((latin adj square) or cross-over).af. 8

14. 8 or 11 or 7 or 13 or 10 or 9 or 12 3202

15. 6 or 14 3202

16. eating disorders.sh. 370

17. anorexia nervosa.sh. 8

18. bulimia nervosa.sh. 6

19. suicide.sh. 743

20. self harm.sh. 365

21. self injury.sh. 83

22. depression.sh. 1731

23. mood disorder$.af. 30

24. bipolar.af. 125

25. "neuroses and phobias".sh. 287

26. anxiety.sh. 39

27. "sleep and sleep disorders".sh. 287

28. community mental health nursing.sh. 69

29. community mental health care.sh. 98

30. mental health.sh. 637

31. mental health community care.sh. 1121

32. mental health services.sh. 2665

33. mental illness.sh. 69

34. schizophrenia.sh. 747

35. psychotic$.af. 288

36. psychos#s.mp. 288

37. (chronic$ adj mental$).ti,ab. 100

38. (sever$ adj mental).ti,ab. 194

39. (mental$ adj disorder$).ti,ab. 276

40. (mental$ adj ill$).ti,ab. 1829

41. limit 40 to yr="1985 - 2008" 1751

42. (emotion$ adj disorder$).ti,ab. 21

43. limit 42 to yr="1985 - 2008" 21

44. paranoid.mp. [mp=title, abstract, heading words] 22

45. limit 44 to yr="1985 - 2008" 21

46. 35 or 33 or 32 or 21 or 26 or 17 or 22 or 18 or 30 or 16 or 23 or 29 or 25 or 27 or 39 or 28 or 36 or 41 or 20 or 38 or 34 or 45 or 37 or 24 or 43 or 19 or 31 10365

47. limit 46 to yr="1985-2008" 9905

48. decision making process.sh. 908

49. limit 48 to yr="1985-2008" 832

50. (share$ adj decision adj mak$).ti,ab. 36

51. limit 50 to yr="1985 - 2008" 32

52. (decision adj analys$).mp. 27

53. limit 52 to yr="1985 - 2008" 26

54. 53 or 49 or 51 877

55. (patient or client or subject or person or consumer).mp. 31096

56. limit 55 to yr="1985-2008" 29362

57. (family or carer).mp. 7670

58. limit 57 to yr="1985 - 2008"

59. (professional or physician or clinician or practitioner).mp. 16361

60. limit 59 to yr="1985 - 2008" 12837

61. (56 and 60) or (60 and 58) 1706

62. (shar$ adj information).mp. 46

63. limit 62 to yr="1985 - 2008" 40

64. (patient adj choice$).mp. 141

65. limit 64 to yr="1985 - 2008" 127

66. (patient adj understanding).mp. 18

67. limit 66 to yr="1985 - 2008" 17

68. ((check or clarify) adj3 understanding).mp. 2

69. limit 68 to yr="1985 - 2008" 2

70. nurses preferences.mp. [mp=title, abstract, heading words] 6

71. limit 70 to yr="1985-2008" 4

72. (treatment adj options).mp. 686

73. limit 72 to yr="1985 - 2008" 635

74. values.mp. 733

75. limit 74 to yr="1985 - 2008" 689

76. preferenc$.mp. 703

77. limit 76 to yr="1985 - 2008" 632

78. (communicat$ adj risk).mp. 5

79. limit 78 to yr="1985 - 2008" 3

80. attitude of health personnel.mp. [mp=title, abstract, heading words] 1

81. limit 80 to yr="1985 - 2008" 1

82. (patient adj expect$).mp. 24

83. limit 82 to yr="1985 - 2008" 22

84. (problem adj definite$).mp. 2

85. limit 84 to yr="1985 - 2008" 2

86. (ask adj question$).mp. 15

87. limit 86 to yr="1985-2008" 13

88. (assess adj risk).mp. 20

89. limit 88 to yr="1985-2008" 18

90. self-manag$.mp. 522

91. limit 90 to yr="1985 - 2008" 473

92. equipoise.mp. 4

93. limit 92 to yr="1985 - 2008" 4

94. 67 or 63 or 71 or 91 or 79 or 87 or 93 or 77 or 65 or 85 or 75 or 83 or 69 or 81 or 73 or 89 2637

95. (decision adj aids).mp. 19

96. limit 95 to yr="1985 - 2008" 17

97. decision support.mp. 77

98. limit 97 to yr="1985 - 2008" 71

99. checklist.mp. 346

100. limit 99 to yr="1985 - 2008" 310

101. 98 or 100 or 96 395

102. (goal adj set$).mp. 49

103. limit 102 to yr="1985 - 2008" 46

104. negotiat$.mp. [mp=title, abstract, heading words] 285

105. limit 104 to yr="1985 - 2008" 273

106. deliberat$.mp. 165

107. limit 106 to yr="1985 - 2008" 157

108. (decis$ and mak$).mp. 2664

109. (decis$ and mak$).mp. 2482

110. consensus.mp. [mp=title, abstract, heading words] 276

111. limit 110 to yr="1985 - 2008" 253

112. concordance.mp. 129

113. limit 112 to yr="1985 - 2008" 113

114. agreement.mp. [mp=title, abstract, heading words] 169

115. limit 114 to yr="1985 - 2008" 155

116. (action adj plan).mp. 119

117. limit 116 to yr="1985 - 2008" 108

118. 111 or 115 or 107 or 109 or 103 or 117 or 105 or 113 3541

119. 'quality of life'.tw. 2512

120. limit 119 to yr="1985 - 2008" 2335

121. (patient adj satisfaction).mp. 690

122. limit 121 to yr="1985 - 2008" 644

123. (follow adj up).mp. 1086

124. limit 123 to yr="1985 - 2008" 1005

125. readmission.mp. 99

126. limit 125 to yr="1985 - 2008" 97

127. (treatment adj (compliance or concordance)).mp. 16

128. limit 127 to yr="1985 - 2008" 15

129. 128 or 124 or 120 or 122 or 126 4064

130. (54 and 61) or (61 and 94) or (61 and 118) or (61 and 129) or (54 and 129) or (94 and 129) 319

131. 15 and 47 and 130 0

CONTRIBUTIONS OF AUTHORS

Edward Duncan: Conceived the review, wrote the title registration form and the protocol. Lead and contributed to all further stages of the review.

Catherine Best : Conducted electronic searches of databases; assessed title and abstracts obtained from electronic and other searches and contributed to the assessment of the methodological quality of the retrieved studies, the analysis of the results and the drafting of the review.

Suzanne Hagen: Provided guidance on preparing the title registration form and protocol. Contributed to the assessment of methodological quality of retrieved studies, analysis of results, and critically read drafts of the review document.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Nursing, Midwifery and Allied Health Professions Research Unit, UK.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

1. In the protocol we stated that we would search the ReFeR database. However this database is no longer supported by the Department of Health so instead we searched the WHO Clinical Trial Portal database of ongoing trials.
2. Various analysis methods were planned were sufficient data gathered. Our pre-planned methods covered topics including unit of analysis, ITT analysis,assessment of heterogeneity and reporting biases, data synthesis, and subgroup and sensitivity analysis. As only two studies were included in the final review and were different in setting, inclusion criteria and intervention these planned analyses were not required. Our methodology is retained in the Data collection and analysis section for application in future updates of the review.

INDEX TERMS

Medical Subject Headings (MeSH)

*Decision Making; *Patient Participation; Depression [*therapy]; Patient Satisfaction; Randomized Controlled Trials as Topic; Schizophrenia [*therapy]

MeSH check words

Humans